

STANDARD OPERATING PROCEDURES

TUBERCULOSIS CONTROL PROGRAM

Iowa Department of Public Health
Bureau of Immunization and Tuberculosis
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CHAPTER 1: IOWA TB CONTROL PROGRAM

PURPOSE

Standard operating procedures (SOP) are intended to provide an overview of the daily standard functions of the Iowa Department of Public Health (IDPH), Tuberculosis (TB) Control Program, hereafter referred to as “the Program.” This SOP standardizes the Program guidelines for cases of latent TB infection (LTBI) and suspected/confirmed cases of TB disease. The SOP is a supplement to the responsibilities of program staff as outlined in each position’s respective Position Description Questionnaire.

This document is also to be used as a tool for IDPH staff outside of the Program desiring to learn the purpose, processes, and procedures of this program. The procedures outlined in this SOP may be changed as necessary, and will be reviewed annually.

SCOPE

The Program is part of the Division of Acute Disease Prevention Emergency Response and Environmental Health (ADPEREH) within the IDPH and a program within the Bureau of Immunization and TB. Tuberculosis control and prevention is an essential function of public health and requires daily case management, investigation, surveillance, and analysis to interrupt the spread of TB disease in Iowa’s population.

The Program provides direct oversight of LTBI and TB disease cases from admission to discharge in the TB Control Program. This includes advanced consultation and direction to physicians, nurses, local public health agencies (LPHAs) and other healthcare providers regarding TB transmission, pathogenesis, treatment, signs and symptoms, infection control practices, and contact investigations. The purpose and scope of responsibilities can be defined by outlining core functions and essential services. The core functions of TB include:

- Disease consultation and education
- Investigation of active or suspect TB cases
- Case management of active TB cases
- Administration of Iowa’s TB Medication Program
- Data management
- Data analysis
- Administration and finance

NATIONAL AND STATE PROGRAM GOALS AND OBJECTIVES

The goal of TB control in the United States, and subsequently Iowa, is to reduce TB morbidity and mortality by doing the following:

- Preventing transmission of *M. tuberculosis* from persons with contagious forms of the disease to uninfected persons
- Preventing progression from latent TB infection (LTBI) to active TB disease among persons who have contracted *M. tuberculosis* infection.

For detailed information on the transmission of *M. tuberculosis* and on how LTBI progresses to TB disease, see the Centers for Disease Control and Prevention's (CDC's) online course, [Interactive Core Curriculum on Tuberculosis](#) (2013).

The four fundamental strategies to reduce TB morbidity and mortality include the following:

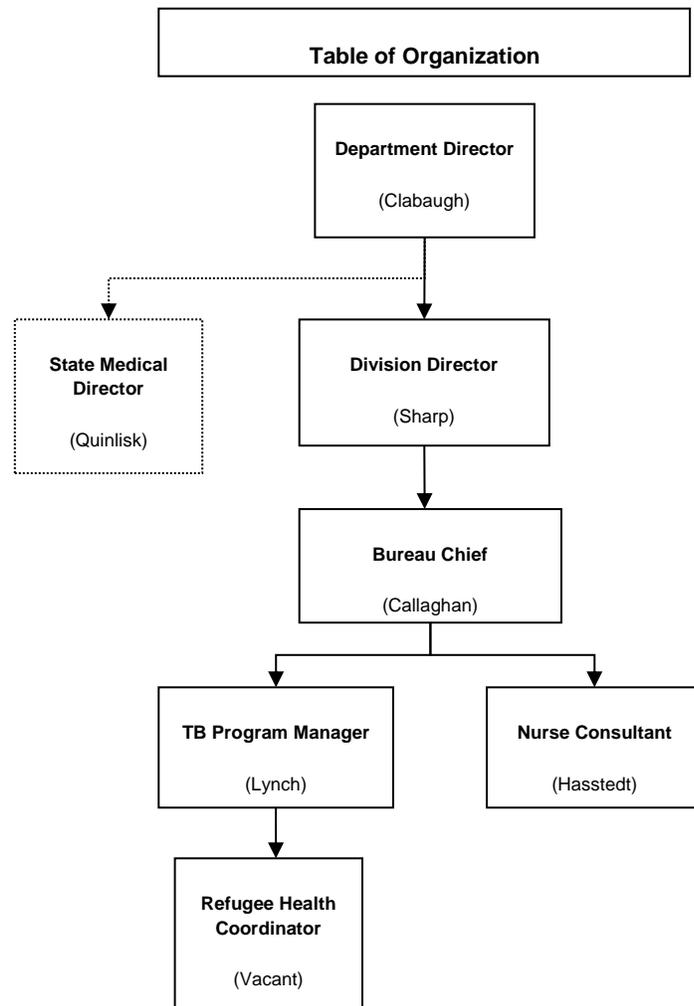
1. Early and accurate detection, diagnosis, and reporting of TB cases, leading to initiation and completion of treatment
2. Identification of contacts of patients with infectious TB and treatment of those at risk with an effective drug regimen
3. Identification of persons with latent TB infection at risk for progression to TB disease and treatment of those persons with an effective drug regimen
4. Identification of settings in which a high risk exists for transmission of *M. tuberculosis* and application of effective infection control measures.

For detailed information on these strategies see "[Controlling Tuberculosis in the United States: Recommendations from the American Thoracic Society, CDC, and the Infectious Diseases Society of America](#)" (MMWR 2005: 54 [No. RR-12])

The general, national TB program objectives reflect the national priorities for TB control in the United States. The 15 high-priority TB program objective categories are:

- Completion of treatment
- Contact investigations
- Laboratory reporting
- Treatment initiation
- Sputum culture conversion
- Recommended initial therapy
- Universal genotyping
- TB case rates (in populations: U.S.-born persons, foreign-born persons, U.S.-born non-Hispanic blacks, and children younger than 5 years of age)
- Data reporting (Report of Verified Case of Tuberculosis [RVCT], the Aggregate Reports for Tuberculosis Program Evaluation [ARPEs], and the Electronic Disease Notification [EDN] system)
- Known HIV status
- Evaluation of immigrants and refugees
- Sputum culture reporting
- Program evaluation
- Human resource development plan
- TB training focal points

TABLE OF ORGANIZATION



AUTHORITY

Iowa Code Chapter 139A.6 and 641 Iowa Administrative Code Chapter 1 provides the local Boards of Health and IDPH with the legal authority to implement TB disease control measures. (Appendix 1)

CHAPTER 2: REPORTING TUBERCULOSIS

LABORATORY AND HEALTHCARE PROVIDER REPORTING REQUIREMENTS

[Iowa Administrative Code 641-1.3-1.4 \(139\)](#) stipulates that laboratory and the healthcare provider must report suspected/confirmed *M. tuberculosis*. (Appendix 1)

WHAT TO REPORT

- Cases of suspected or lab confirmed pulmonary and extrapulmonary TB disease should be reported to IDPH within one working day.
- Latent tuberculosis infection (LTBI) is not reportable in Iowa.

HOW TO REPORT

The Program requests that TB cases be reported by phone to help ensure timely public health follow-up measures. Alternatively, faxed notification is acceptable. Laboratory specimens should be submitted directly to the SHL for rapid diagnosis of *M. tuberculosis* complex, culture speciation, drug susceptibility testing, and genotyping.

Phone: Nurse Consultant: 515-281-8636
Program Manager: 515-281-7504

Fax: TB Control Program Secure Fax 515-281-4570

SHL: [State Hygienic Lab information on how to submit samples](#)

TB DISEASE CASES

Cases that meet the current CDC surveillance case definition of verified TB are counted by the Program Manager and reported in IDSS. The Program Manager is the only official with the authority to report cases in IDSS and transmit to CDC. For detailed overview of the guidelines for counting TB Cases, see [Recommendations for Counting Reported Tuberculosis Cases](#).

CHAPTER 3: CASE MANAGEMENT

Case management of TB disease describes the activities undertaken by the Program and the LPHA to ensure successful completion of TB treatment and cure of the patient. Case management, under the umbrella of IDPH, is a system in which a specific LPHA is assigned primary responsibility for the TB patient and IDPH program staff (Nurse Consultant) are assigned systematic regular review of patient progress.

The LPHA is responsible for the majority of patient monitoring and ensuring the quality of all TB case management. The Program will ensure that medical treatment is in compliance with current CDC/ATS and IDSA guidelines for the treatment of TB disease. The Program will verify all reported cases meet the definition for public health surveillance, assign and evaluate contact investigations as appropriate, monitor progress, and implement corrective action as needed for stated program performance objectives.

The Program provides the LPHA with guidance on TB case management of LTBI and TB disease to include:

- Testing and identification of LTBI and suspect/confirmed TB
- Providing directly observed therapy (DOT) incentive funds for qualifying cases
- Monitoring adverse reactions to antituberculosis medications
- Monitoring bacteriologic and clinical improvement

LOCAL HEALTH DEPARTMENT RESPONSIBILITIES

The Program contacts the local public health nurse (LPHN) or designee and/or treating clinician to determine treatment plans, document response to therapy, non-adherence issues, adverse drug reactions, and TB discharge planning. Effort should be made to have the LPHN or designee as the point of contact to the treating clinician. The purpose for this is to establish competence in TB control principles at the local level as well as provide the treating clinician direct access to their counterpart serving the patient.

The Program provides relevant consultation and education to the LPHN or designee to enable them as the point of contact. If the LPHN or designee is not able to effectively communicate with the treating clinician, the Program should work directly with the treating clinician.

PROVIDING INTERPRETATION TO LIMITED ENGLISH PROFICIENT (LEP) INDIVIDUALS:

Authority: Title VI of the Civil Rights Act of 1964; Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency

All recipients of federal funds and all federal agencies are required by law to take reasonable steps to provide meaningful access to limited English proficient persons. Individuals who do not speak English as their primary language and who have a limited ability to read, speak, write, or understand English can be limited English proficient, or "LEP." These individuals are entitled to language assistance with respect to obtaining needed medical services. Language assistance is especially important when providing clinical case management of LTBI and TB disease.

Recommendations: Local public health agencies serving patients with LTBI and TB disease should determine the language needs of these patients at the first point of contact. LPHA should use a qualified interpreting service to reasonably ensure that medical and legal information is fluently and effectively communicated in both English and the primary or preferred language of the LEP patient. Qualified interpreting services include, but are not limited to, telephone interpreting services. These services must be provided at no cost to the LEP patient.

LPHAs that receive DOT incentive funding and or medical evaluation funding are obligated to use a qualified interpreting service while providing clinical case management for LTBI and TB disease. Failure to provide this service may result in the withdrawal of DOT incentive and or medical evaluation funding.

For more information on Title VI see:

- [Title VI of the Civil Rights Act of 1964](#)
- [LEP.GOV](#)

LATENT INFECTION (LTBI)

LTBI is not a reportable condition in Iowa. However, the Program provides medication to treat LTBI, regardless of income status of the patient. Upon identification of LTBI the Program:

- Reviews all prescriptions and chest x-ray reports to ensure compliance with current treatment guidelines
- Counsels providers/public health nurses on treatment adherence/adverse drug reactions
- Orders medication from the state pharmacy and documents case in TB Meds program

TIME FRAMES CXR/CT

LTBI medication orders require a medical evaluation including a current chest x-ray or CT that rules out TB disease. The CXR and/or CT is the chief means for a clinician to rule out pulmonary TB disease. A complete medical evaluation is used to rule out extrapulmonary TB. The Program requires a chest x-ray or CT scan performed in the United States to obtain LTBI medications. Timeframes in which the chest x-ray or CT were completed until medications are ordered differ depending on the patient's risk factors.

Six months: No identified risk factors

3 months: Any identified risk factor including:

- | | | |
|-----------------------|---|--|
| 5mm TST
Positives | { | <ul style="list-style-type: none">• HIV/AIDS infection• Close contacts of a person with infectious TB disease (as identified in public health investigation)• Person with changes to CXR consistent with prior TB• Organ transplants or other immunosuppressed people• Specialized treatment (i.e. meds that depress immune system) for rheumatoid arthritis or Crohn's disease |
| 10mm TST
Positives | { | <ul style="list-style-type: none">• Persons who have immigrated (within the last 5 years) from areas of the world with high rates of TB• Children less than 5 years of age who have a positive TB test• Groups with high rates of TB transmission, such as homeless persons, injection drug users, and persons with HIV infection• Persons who work or reside with people who are at high risk for TB in facilities or institutions such as hospitals, homeless shelters, correctional facilities, nursing homes, and residential homes for those with HIV• Substance abuse• Silicosis (occupational exposure to stone dust: mining, sandblasting, quarry, ceramics and foundry workers, as well as grinders, stone cutters, refractory brick workers, tombstone workers, pottery workers)• Diabetes mellitus• Severe kidney disease• Low body weight (less than 10% of Ideal)• Head and neck cancer• Medical treatments such as corticosteroids or organ transplant |

TUMOR NECROSIS FACTOR-ALPHA (TNF-ALPHA) ANTAGONISTS AND THE INCREASED RISK OF TB:

See the [Heartland Fact Sheet](#) for specific recommendations on LTBI and TNF-A. In general, patients should complete at least 30 days of LTBI treatment prior to starting TNF-A treatment. This population of patients are eligible for the 12- Dose LTBI option.

TUBERCULOSIS DISEASE

INTAKE PROCEDURE FOR INFECTIOUS SUSPECTED/CONFIRMED TB:

All pertinent patient history and physical, lab, and X-ray/CT information is requested from the treating clinician or facility.

The Program initiates completion of the '[TB Suspect/Active Patient Intake Form](#)' (Appendix 2) for all suspected/confirmed cases of active TB disease. If data is not available at intake, document date(s) request made to obtain information. If no information for a variable/field is obtained after three request, document and report to the Program Manager for further follow up.

The Program, in cooperation with LPHAs and private clinicians, determines if a person meets criteria for infectious TB. If the criteria for infectiousness are met, the Program will make recommendations to the LPHA to issue the appropriate isolation and/or treatment orders. See *Chapter 5 – Isolation* for guidance on isolation procedures including issuance of legal isolation orders.

INTAKE PROCEDURE FOR SUSPECTED/CONFIRMED EXTRAPULMONARY TB:

Intake procedures are the same for suspected/confirmed cases of extrapulmonary TB as pulmonary cases with the exception of isolation control measures and subsequent monitoring of sputa.

Documentation of a clinician's statement that pulmonary TB has been ruled out is required. No issuances of legal orders are necessary for extrapulmonary cases. Exception to this rule is extrapulmonary cases with co-morbidity of HIV/AIDS. This circumstance requires individual case review, and if deemed appropriate, issuance of a treatment completion order executed.

INTER-JURISDICTIONAL REFERRALS

TB Disease

The Program is responsible for transfer of TB disease case notifications between states and other LPHAs within Iowa. The LPHAs should notify the Program when a patient plans or requests to transfer to another jurisdiction. The receiving and referring jurisdictions should stay in communication until final dispensation of the patient is known.

Patients with infectious TB are not allowed to move to another jurisdiction by commercial transportation. Generally, patients with infectious TB are discouraged from moving to another jurisdiction until they meet criteria for non-infectiousness. However, if infectious TB patients request permission to move to another jurisdiction, the Program is obligated to honor the request as long as appropriate precautions are taken to assure the general public is not exposed. The Program should notify the jurisdictional state health department of such intention utilizing the inter-jurisdictional notification form found on the [National TB Controllers Homepage](#).

Giving the patient two to four weeks of travel medications is standard. Each case should be discussed with the treating clinician in advance of the transfer of care. Infectious TB patients are free to travel by private transportation to their next arrival destination. All relevant treatment records to include any legal orders should be sent to the receiving jurisdictional health department.

LTBI

Movement from one LPHA in Iowa to another can be accomplished at the local level with notification to the Program. If there is out of state notification needed, the LPHA should notify the Program to include, address in new state, phone number, emergency contact, date leaving and date expected in the new jurisdiction. The Program will contact the receiving jurisdiction to determine follow-up.

CHAPTER 4: TREATMENT OF LTBI/TB DISEASE

TB MEDICATION POLICY

Purpose: The Tuberculosis Medication policy is utilized by the TB Program to assure TB medications are available to all individuals diagnosed with LTBI or TB disease provided adequate funding exists. The Program shall utilize three options purchasing of health insurance and/or payment of associated co-payments.

Authority: IAC: 641-170.7(2)e includes the provision for the TB Program to dispense TB medications and provide medical consultation and education to clinical providers.

Ensuring Payer of Last Resort: The TB Program will utilize this policy to pursue the most cost effective means to supply medications while ensuring appropriate treatment of LTBI and TB cases. The Program will work with local public health agencies (LPHA), LPHA designated agencies, or other health care provider organizations to verify patient insurance status or options available to secure medications for patients.

Funding Source: The funding source utilized for these activities is from state appropriations. The funds for these activities are not from an entitlement program and does not create a right to assistance. In the event funding is exhausted or terminated, or there are changes in state or federal guidelines, programs, or regulations that impact funding available to the TB Program, the Department reserves the right to cease providing medication or health insurance assistance, or alter eligibility criteria until such time that funding is again sufficient. Eligibility criteria may be prioritized based upon impact to public health and to prevent the transmission of TB disease.

Rationale: The TB Program manages the treatment of LTBI and TB patients due to the following reasons: complexity of treatment regimens, need to verify proper treatment/medical prescriptions from health care providers, ensure proper duration of treatment and to ensure TB patients take all prescribed medications (Directly Observed Therapy). To ensure proper diagnosis, treatment and cure, the TB Control Program shall coordinate appropriate medications for all patients diagnosed with LTBI and TB disease. Proper diagnostic evaluation and treatment of LTBI and TB disease is complicated and requires consultation with experts in the medical case management of LTBI and TB disease. The TB Program provides this consultation to clinicians for suspected and confirmed LTBI and TB disease cases from intake until cure.

Patient Treatment: The order in which patients are reviewed and medications activities are coordinated to obtain medications is based upon order in which cases are identified/reported throughout the year.

TB Medication Procurement: The Program shall utilize three options for the procurement of tuberculosis medications: state procurement of TB medication, billing of health insurance, and the purchasing of health insurance and/or payment of associated co-payments.

State Procurement of TB Medications: All patients with a TB Program verified diagnosis of LTBI or TB disease are eligible to receive TB medications regardless of income status. A Department contracted pharmacy will receive, process and ship all TB medications at the written direction of the TB Program based upon a prescription from the treating physician. The contracted pharmacy ships TB medications only to LPHAs or clinics for distribution to patients. Patients are not charged for any portion of the medications. Reimbursement is not available to patients for medications purchased from any other source.

Billing of Insurance: The Program may bill insurance (if available) for the following subset of TB patients in order of priority. The Program will seek the most cost effective means of providing medication when determining whether to bill insurance (State purchased medication vs. billing insurance). The priority order below directly correlates to treatment costs with MDR/XDR TB disease being the most costly.

1. MDR/XDR TB Disease
2. TB Disease (any drug resistance)
3. TB Disease (pan sensitive)
4. LTBI patients on any medication other than mono INH

Purchasing Insurance for Patients without Coverage: The Program may purchase insurance and cover co-payments for patients when the patient does not have insurance and the cost of medications exceeds the cost of purchasing insurance. This instance rarely occurs (six cases /16 years) and is likely for the treatment of MDR/XDR TB cases only. Average medication costs to treat MDR-TB patients is \$40,000 - \$50,000 compared to \$500 for patients with TB disease.

LTBI

Shipping: For LTBI medications, the entire course of treatment (6 or 9 months) is sent to the LPHA at initiation of treatment because of cost savings over multiple mailings of medications. The cost of shipping and staff time outweighs savings in medication if patient subsequently does not start/stops taking medication.

Processing of LTBI medication requests: Properly completed LTBI orders will be processed as soon as possible (not to exceed 5 business days). If LTBI orders are submitted to the Program and information is missing or incomplete, the Program will call or fax a request for missing/incomplete information back to the provider's office within a reasonable timeframe. Completed orders are entered into the TB Meds program and submitted to the contractual pharmacy for distribution.

Ruling out TB disease: The Program Manager or Nurse Consultant must sign/date each CXR to indicate active disease has been ruled out. If the CXR does not clearly rule out TB disease, contact the clinician to obtain a written statement indicating that TB disease is ruled out. No LTBI medications are issued that lack this clarity.

Monitoring: LPHA should distribute no more than 30 days of medication at a time to the patient. At monthly intervals, the LPHA assesses patients being treated for possible adverse reactions to the medication, especially those associated with drug-induced hepatotoxicity. LPHAs should utilize the '[LTBI Monitoring Flow Sheet](#)' or similar form to document any clinical concerns. Patients who have adverse reactions, especially those consistent with drug-induced hepatotoxicity should immediately stop taking medication and see their healthcare provider.

Private clinics/MD offices: The same recommendation for monthly monitoring for patients receiving treatment for LTBI applies to these settings. If the clinic releases the entire prescription to the patient, documentation should occur if known.

Patients temporarily leaving jurisdiction: Patients leaving the area for durations greater than 30 days may be given no more than 30 days of travel medications due to necessity of monitoring for adverse reactions to medication. LPHAs intending to give greater than 30 days should seek approval of the treating clinician.

Patients moving to another state: The Program sends an inter-jurisdictional referral (IJR) to the receiving state TB Control program. IJR should include chest x-ray report, prescription and medication record. Thirty days of travel medications are given to the patient. Patients on intermittent therapy (e.g., less than daily medication administration) may be given less than 30 days of travel medications. This decision will be made on a case-by-case basis.

For detailed information of the treatment of LTBI see the following CDC Fact Sheets:

- [Treatment of LTBI](#)
- [LTBI treatment Options](#)

TB DISEASE

GENERAL RECOMMENDATIONS

General CDC/ATS and IDSA recommendations include starting patients on a standard four-drug regimen of Isoniazid (INH), Rifampin (RIF), Ethambutol (EMB) and Pyrazinamide (PZA) if the patient's drug sensitivities are unknown or are pan-sensitive. If treatment variance to these recommendations occurs, the Program must resolve the variance with the treating clinician and if unable to do so, involve the TB Medical Consultant (Dr. Hornick), State Medical Director or designee, or Mayo Clinic Center for Tuberculosis.

For detailed information on the current treatment recommendations for TB, use the following guidelines: [Treatment of Tuberculosis: American Thoracic Society, CDC, and Infectious Diseases Society of America](#), [Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis](#), and the [Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children](#).

Processing of TB disease medication requests: Properly completed orders will be processed as soon as possible (not to exceed one business day). If orders are submitted to the Program and information is missing or incomplete, the Program will call for the provider's office to obtain the missing/incomplete information within one business day. Once complete orders have been entered into TB Meds program they will be submitted to the contractual pharmacy for distribution.

MONITORING OF TB CASES

The Program or the LPHA shall obtain all relevant health/physical assessments, demographic, laboratory and discharge information from the Infection Control Practitioner (ICP) or other designee. This information is used to complete the '*TB Suspect/Active Intake Form*' (Appendix 2) upon notification of TB case. Periodically throughout the course of treatment the Program will consult with the LPHA as follows:

- **Initial Phase of Treatment:** The Program will contact the LPHN or designee and/or provider at least one time weekly. After care is established, contact intervals may be lengthened as mutually agreed upon by both parties.
- **Continuation Phase:** The Program will contact the LPHN or designee and/or provider at least monthly.

At a minimum, monthly documentation includes basic narrative format noting any adverse reactions to TB medications and monitoring bacteriologic and clinical improvement.

DIRECTLY OBSERVED THERAPY

Directly observed therapy (DOT) is the standard of care for all patients in TB control programs in the United States and should be provided by the LPHN or designee.

Eligibility of LPHAs for DOT incentive funding may vary from funding cycle to funding cycle; but generally, all infectious (pulmonary and laryngeal), HIV+, and childhood cases of TB disease are eligible. Documentation of TB doses administered by DOT vs. self-administered is part of the case management process for all TB patients. LPHAs may use the '[DOT Tracking Log.](#)' (Appendix 6) but if not, are expected to have documentation of doses administered.

It is the expectation that LPHAs accepting incentive funding for DOT will perform DOT with the patient until treatment completion. Regardless of availability of incentive funding, DOT remains the standard of care. The CDC/ATS and IDSA recommend all healthcare providers implement DOT on each active case of TB

LPHAs that receive DOT incentive funding and or medical evaluation funding are obligated to use a qualified interpreting service while providing clinical case management for LTBI and TB disease. Failure to provide this service may result in the withdrawal of DOT incentive and or medical evaluation funding.

COUNTING DOT DOSES

There are two main citations from CDC/ATS/IDSA MMWR *Treatment of Tuberculosis* on this subject that seemingly contradict one another. Both citations are referenced below. In summation, the contention is how to count weekend dosing for those patients receiving daily therapy.

- One point advocates 5 days/week DOT dosing, adding missed doses to the end of treatment.
- The other point advocates 5 days/week DOT dosing but not adding missed doses to the end of treatment. Option is given to allow patients to self-administer weekend doses.

The Program accepts either position as effective treatment. However, the Program's preference is for patients receiving daily therapy to have 5 days/week DOT dosing, with patients self-administering weekend doses. This should be documented as 5 day/week DOT. Report this method as "100% DOT" in RVCT.

Source: [MMWR; Treatment of TB June 20, 2003/vol. 52 section: 5.2.1.](#): "Based on substantial clinical experience 5 days-a-week drug administration by DOT is considered to be equivalent to 7 day-a-week administration, thus, either may be considered "daily." Although administration of antituberculosis drugs by DOT at 5 days/week, rather than 7 days, has been reported in a large number of studies it has not been compared with 7-day administration in a clinical trial and therefore is rated 'AIII'." (Approved drug treatment regimes range from A(I), most preferred, to E(I), least preferred).

Source: [MMWR; Treatment of TB June 20, 2003/vol. 52 section: Completion of Treatment \(page 8\).](#) "Clinical experience suggests that patients being managed by DOT administered 5 days/week have a rate of successful therapy equivalent to those being given drugs 7 days/week. Thus, "daily therapy" may be interpreted to mean DOT given 5 days/week and the required number of doses adjusted accordingly. For example, for the 6-month "daily" regimen given 5 days/week the planned total number of doses is 130. (Direct observation of treatment given 5 days/week has been used in a number of clinical trials, including USPHS Study 22, but has not been evaluated in a controlled trial; thus, this modification should be rated AIII.) As an option, patients might be given the medications to take without DOT on weekends."

FREQUENCY OF SPUTUM COLLECTION

Sputum's should be collected on pulmonary TB patient until sputum culture conversion is documented. Sputum culture conversion is reached when sputum specimens consistently (series of three preferred) no longer culture TB. Sputum culture conversion should be documented by the end of the initial phase of treatment (first 60 days of TX);

If culture conversion is not previously documented, collect a series of sputum's at ~ days 58 – 60 of treatment. Guidelines recommend extension of treatment (additional 90 days) for patients with cavitary lesions **and** failure to convert sputum cultures within 60 days of treatment initiation.

- **For patients with positive sputum smears** - after treatment is initiated sputum collection is at approximately days 13, 14 and 15 of treatment and then at least every two weeks until the patient meets criteria for non-infectiousness.
- **Patients whose sputum specimens are initially negative on smear-** after treatment is initiated sputum collection is at approximately days 13, 14 and 15 of treatment followed by monthly specimen collection until cultures have converted to negative.
- **Culture Conversion:** After culture conversion has been documented, no further sputum collection is necessary unless there is a clinical indication (e.g., recurrence or persistence of TB-like symptoms or treatment interruption). Individuals with MDRTB or HIV-TB may require additional sputum testing to monitor their clinical course.

RECOMMENDATIONS FOR SPUTUM COLLECTION TABLE

Purpose	Frequency	Number of specimens
Initial Monitoring for smear conversion	Days 13 – 15 of TX, then every 2 weeks - monthly	3 samples, collected at least 8 hours apart. Preference is 3 first AM specimens/different days
Monitoring for culture conversion	Monthly	3 samples on three different days -
Monitoring after culture conversion	Only if clinically indicated	3 samples on three different days -

HOSPITALIZATION VERSUS OUTPATIENT CARE

Need for Hospitalization

Hospitalization is not necessary for TB to be diagnosed or treated, unless clinically indicated.

Airborne Precautions in Hospital Setting

Hospitalized patients in whom infectious (i.e., pulmonary or laryngeal) TB is suspected should be placed in an airborne-infection isolation (All) room and should wear a surgical mask during transport and in waiting areas.

Health care workers and visitors entering the isolation room should wear at least N95 disposable respirators, as should health care workers performing procedures such as sputum induction, bronchoscopy, jet irrigation of abscesses, and autopsies.

[NTCA/APHL Consensus Statement on the Use of Cepheid Xpert MTB/RIF Assay in Making Decisions to Discontinue Airborne Infection Isolation in Healthcare Settings](#): This consensus statement provides detailed guidance on when to discontinue/continue AI for patients with suspected pulmonary TB disease. In general, patients with two negative TB NAAT results meet criteria to be released from AI.

Related guidance: [Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007](#)  See Appendix A

Airborne Precautions for Outpatient Care

Patients who have not met criteria for non-infectiousness should wear a general surgical mask to all appointments for required health care. Arrangements should be made in advance of healthcare appointments to ensure patients with infectious TB do not sit in general waiting area with other patients and instead are immediately escorted into an All room.

Routine appointments for medical care should be delayed until the patient has met criteria for non-infectiousness.

HIV AND TB

All patients with TB should have counseling and testing for HIV infection. People infected with HIV are more likely than uninfected people to get sick with TB disease.

- Among people with latent TB infection, HIV infection is the strongest known risk factor for progressing to active TB disease
- A person who has both HIV infection and active TB disease has an AIDS-defining condition
- All persons should be tested for LTBI at the time of HIV diagnosis, regardless of their epidemiological risk of TB exposure. For current guidelines on the treatment of TB disease in a HIV co-infected person [click here](#).

CHAPTER 5: PUBLIC HEALTH NOTIFICATIONS AND ORDERS

INTRODUCTION

The following is an overview of TB Control Program recommendations for issuing public health notifications and orders for patients with infectious (pulmonary/laryngeal) TB. Notifications are issued for voluntary cooperation to detail compliance with confinement and treatment responsibilities of patients with infectious TB. Orders are issued when patients are non-compliant with voluntary confinement and or treatment notifications. Local public health agencies (LPHA) may use these templates, modify or develop their own versions.

Patients with TB disease have unique circumstances that may require modification of these general public health notifications and orders. Each LPHA should consult with their Local Board of Health and legal counsel in advance of issuing public health orders. Non-compliance or refusal of treatment while patients are infectious constitutes an immediate public health measure to isolate the patient from the public. This may or may not warrant isolation to a facility (jail, hospital or other designated facility).

The following is the typical progression of issuing public health notifications and orders:

1. *Notification of Voluntary Home Confinement for Infectious Tuberculosis (TB)*
2. *Notification of Voluntary Treatment Responsibilities for Infectious Tuberculosis (TB)*
3. *Warning Letter* - issue if non-compliance of *Voluntary Confinement* and *Treatment* notifications/orders are significant
4. *TB Home Isolation Order* - issue if terms of *Warning Letter* are not followed
5. *TB Treatment Order* - issue if terms of *Warning Letter* are not followed
6. *TB Facility Isolation Order* - issue if above notifications and orders fail

NOTIFICATIONS FOR VOLUNTARY HOME CONFINEMENT AND TREATMENT

The Program recommends LPHA issue both the *Notification of Voluntary Home Confinement for Infectious Tuberculosis (TB)* and the *Notification of Voluntary Treatment Responsibilities for Infectious Tuberculosis (TB)* for all patients at the initiation of treatment for infectious TB. The distinction between *Confinement* and *Treatment* notifications exist to emphasize the necessity for public health confinement while infectious, *versus* the obligation of the patient to complete treatment for TB disease until cured.

Issue the following two documents upon diagnosis of an infectious TB patient.

1. Notification of Voluntary Home Confinement for Infectious Tuberculosis (TB)

This is a public health notification issued by the LPHA to the patient at the time of diagnosis of infectious TB. This notification details voluntary compliance with home confinement. The notification factually describes requirements of the home confinement notification, and the medical criteria necessary for release from home confinement.

Release from Voluntary Home Confinement: LPHA are obligated to release patients from the home confinement notification upon meeting criteria for non-infectiousness (see [Criteria for Non-Infectiousness page 25 of SOP](#)). This obligation by LPHA includes sputum collection as recommended in the TB Control Program Standard Operating Procedure (see [Frequency of Sputum Collection - page 18 of SOP](#)). Documentation of release from home confinement is accomplished by the signature and date of the LPHA representative.

2. Notification of Voluntary Treatment Responsibilities for Infectious Tuberculosis (TB)

This notification details voluntary compliance with treatment responsibilities. The Program recommends LPHA issue this notification in conjunction with the Notification of Voluntary Home Confinement for Infectious Tuberculosis (TB).

Release from Voluntary Treatment: LPHA release patients from the voluntary treatment notification upon completion of prescribed treatment. Completion of treatment occurs when, in the opinion of the TB Control Program (and the state public health medical director and epidemiologist) the person's tuberculosis is cured or such person is no longer a threat to public health. Documentation of release from the voluntary treatment notification is accomplished by the signature and date of the LPHA representative.

TB WARNING LETTERS

This step is taken when violation of either *isolation* or *treatment notifications or orders* are significant enough to warrant notifying the patient of further legal consequences. LPHA should document factual non-compliance of the confinement, isolation or treatment notifications/orders in a letter to the patient. Examples of non-compliance include, but are not limited to; missed DOT appointments, missed clinical appointments, failure to cooperate with diagnostic evaluations including recommended sputum collection and/or CXR examination. LPHA document efforts to treat the patient according to the public health notifications and/or orders

1. Non-compliance - Voluntary Home Confinement

If at any time the patient does not comply with the home confinement notification, LPHA may issue a *Warning Letter* detailing the factual violations of the home confinement notification and the ramifications of continued non-compliance. Consultation with the Program, Local Board of Health and legal counsel may be necessary. Continued non-compliance with the home confinement notification may necessitate issuance of an *Isolation Order*.

2. Non-compliance - Voluntary Treatment

If significant non-compliance with the *Voluntary Treatment* notification occurs, issuance of a *Warning Letter* detailing the factual violations of the *Voluntary Treatment* notification and the ramifications of continued non-compliance. Continued non-compliance with the *Voluntary Treatment* notification may necessitate issuance of a *Treatment Order*. Consultation with the Program, Local Board of Health and legal counsel may be necessary.

TB ORDERS FOR NON-COMPLIANT PATIENTS

1. TB Home Isolation Order

This is a public health order issued by the LPHA when the patient **does not** comply with the voluntary confinement notification. The order factually describes requirements of the public health isolation order, and the medical criteria necessary for release from the order. Reference to complying with the *Treatment Order* is noted. Issuance of a *TB Treatment Order* should occur at the same time as issuance of the *TB Home Isolation Order*.

Release from the TB Home Isolation Order: LPHA are obligated to release patients from the *TB Home Isolation Order* upon patients meeting criteria for non-infectiousness (see [Criteria for Non-Infectiousness p. 25 of SOP](#)). This obligation by LPHA includes sputum collection as recommended in the TB Control Program Standard Operating Procedure (see [Frequency of Sputum Collection - p. 18 of SOP](#)). Documentation of release from the *TB Home Isolation Order* is accomplished by signature/date of the LPHA representative.

2. TB Treatment Order:

This is a public health order issued by the LPHA when the patient **does not** comply with the voluntary treatment notification.

Release from Treatment Order: LPHA release patients from the *TB Treatment Order* upon completion of treatment. Completion of treatment occurs when in the opinion of the TB Control Program (and the state public health medical director and epidemiologist) the person's tuberculosis is cured or such person is no longer a threat to public health. Documentation of release from the *TB Treatment Order* is accomplished by the signature and date of the LPHA representative.

TB ORDERS FOR NON-COMPLIANT PATIENTS - FACILITY

If at any time, the patient does not comply with the *TB Isolation Order* or *TB Treatment Order*, issuance of a *Warning Letter* detailing the factual violations of the *TB Isolation Order* and the ramifications of continued non-compliance. Non-compliance of a *these orders* may result in a *TB Facility Isolation Order*. Consultation with the Program, Local Board of Health and legal counsel is recommended.

1. TB Facility Isolation Order:

This is a public health order of last resort that confines a patient to a facility against their will. LPHA should isolate patients in the facility for the duration of treatment unless alternative means of assuring treatment are arranged by the LPHA. *Facility* is defined broadly, as no TB isolation facility exists in Iowa. Each Local Board of Health/LPHA needs to determine an appropriate facility that can manage the terms of the isolation.

Release from Facility Isolation: LPHA release patients from the *TB Facility Isolation Order* upon completion of treatment. Completion of treatment occurs when in the opinion of the TB Control Program (and the state public health medical director and epidemiologist) the person's tuberculosis is cured or such person is no longer a threat to public health. Documentation of release from the *TB Treatment Order* is accomplished by the signature and date of the LPHA representative.

AUTHORITY TO ISSUE NOTIFICATIONS AND ORDERS

Iowa Administrative Code 641.1

1.9(1) Examination, testing, and treatment of quarantinable diseases.

d. A person diagnosed with or clinically suspected of having infectious tuberculosis shall complete voluntary treatment until, in the opinion of the attending physician or the state public health medical director and epidemiologist, the person's tuberculosis is cured or such person is no longer a threat to public health. If such person refuses to complete the course of voluntary treatment, the Department or local board of health may issue an order compelling mandatory treatment. Such order shall include the identity of the person subject to the mandatory treatment order, a description of the treatment ordered, the medical basis upon which the treatment is ordered, and a description of the potential medical and legal consequences of violating such order. A person who violates a mandatory treatment order may be subject to the penalties provided in Iowa Code section 135.38 or 137.21 and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter.

e. A person diagnosed with extrapulmonary tuberculosis or clinically suspected of having infectious tuberculosis who fails to comply with a physician's recommendation for diagnostic testing may be ordered to undergo diagnostic testing by the Department or local board of health. Such order shall include the identity of the person subject to mandatory diagnostic testing, a description of the diagnostic testing ordered, the medical basis upon which the diagnostic testing is ordered, and a description of the potential medical and legal consequences of violating such order. A person who violates a mandatory diagnostic testing order may be subject to the penalties provided in Iowa Code section 135.38 or 137.21 and may be placed under mandatory quarantine or isolation in accordance with the provisions of this chapter.

EMERGENCY ACTION TRIGGERS

- An infectious patient (lab confirmed or clinically suspected) attempts to board commercial transportation or is attempting access to public accommodation (i.e., shelters)
- A person under a *'Facility Isolation Order'* (issued by IDPH or local board of health) attempts or has left the facility
- A person with infectious TB displays flagrant attempt to expose the public to TB
- An infectious person under home isolation order violates the conditions of their order and the recourse is facility isolation

DO NOT BOARD/LOOKOUT REQUEST

A public health 'Do Not Board' (DNB)/Lookout (LO) listing prevents a person with a communicable disease, such as infectious TB, from traveling via commercial aircraft. The DNB/LO list, enforced through the Department of Homeland Security Transportation Security Administration (TSA), applies to all domestic commercial flights and international commercial flights that are departing from or arriving into the United States. The DNB/LO applies to both U.S. citizens and foreign nationals. Detailed guidance for DNB/LO list is available in **Appendix 10**.

Criteria for DNB/LO lists:

Contagiousness: Public health officials must reasonably believe that the individual is contagious, or likely to become contagious by the time of travel, with a communicable disease that could constitute a public health threat should the individual be permitted to travel on a public conveyance or travel internationally.

Nonadherent or unaware: Public health officials must reasonably believe that the individual is unaware of, or will be noncompliant with, public health recommendations against travel. Typical evidence to support nonadherence includes disregard of an isolation recommendation or order, noncompliance with treatment, or evidence that the individual has compelling reasons to travel before receiving clearance by public health authorities.

Intent to travel: Public health officials must reasonably believe that the individual will attempt to fly on a commercial aircraft and/or travel across an international land border, as supported by a history of frequent travel, record of ticket purchase, new ticket reservation, or stated intent to travel by commercial aircraft by the individual, a relative, or other credible source.

STEPS FOR IDPH PLACING INDIVIDUAL ON DNB LIST

1. LPHAs should direct request for DNB orders to the Program.
2. The Program Manager will determine if the individual meets criteria for inclusion in the DNB lists based on above criteria.
3. The Program Manager contacts the Bureau Chief and informs of the intent to place an individual on the DNB list.
4. The Program Manager notifies the Medical Director/Division Director/Attorney General Office of the situation to gain consensus on the decision to place an individual on the DNB list.
5. If consensus is reached to place an individual on the DNB list, the Program Manager follows the procedure for requesting a conference call with CDC Chicago Quarantine Station at 773-894-2960 (24-hour access). Alternate number is the CDC Emergency Operations Center at 770-488-7100.

CDC estimates it takes 9 hours from official request until a person is placed on a DNB/LO.

FOLLOW-UP AND PERIODIC REVIEW OF DO NOT BOARD/LOOKOUT LIST

1. Inform the individual verbally (if possible), once the DNB/LO has been issued. CDC will notify the individual in writing. If appropriate, the state or local jurisdiction may document this action in writing as well.
2. Assist the individual in meeting requirements for removal from the DNB/LO lists.
3. Review the individuals clinical data as appropriate to determine if criteria for non-infectiousness and removal from DNB/LO list is achieved.

REMOVING A PERSON FROM DO NOT BOARD/LOOKOUT LIST

1. Notify the CDC Quarantine Station in your area as soon as criteria for DNB/LO removal is met.
2. Inform the individual verbally once the DNB/LO has been rescinded. CDC will notify the individual in writing. If appropriate, the state or local jurisdiction may document this action in writing as well.

NON-INFECTIOUSNESS DIFFERENCE OF OPINION

At times, the treating clinician will not agree with the Programs assessment that a patient is infectious or has/has not met criteria for non-infectiousness. In these situations the Program/LPHA should consult with the clinician outlining the position from a public health standpoint - citing published CDC/ATS guidelines, review of lab results, and overall clinical picture.

The Program follows these published guidelines and is responsible for ensuring infectious patients do not expose the public. Likewise, this necessitates release from confinement or isolation when the patient is no longer infectious. The LPHA and clinician should make every effort to gain consensus on the infectious status of patients. If consensus is not reached, the Program or LPHA's obligation to confine or isolate and subsequently release from confinement or isolation supersedes a clinician's determination on a patient's degree of infectiousness. A key component to communicate to the clinician is the distinction between a legal order from the LPHA/IDPH –the Program vs. a medical decision by a clinician.

CHAPTER 6: CONTACT INVESTIGATIONS

GOALS

A contact investigation is the process of identifying, examining, evaluating, and treating all persons who are at risk for infection with TB due to recent exposure to a newly diagnosed case of infectious TB. LPHAs are responsible for identifying persons in need of evaluation. For detailed overview of contact investigations, including testing guidelines, assigning contact priority, evaluation, treatment options, and follow up of specific groups of contacts, refer to: [Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis Recommendations from the National Tuberculosis Controllers Association and CDC.](#)

A contact investigation is recommended for the following forms of confirmed TB because they are likely to be infectious:

- Pulmonary or laryngeal disease, with or without pulmonary cavities, and respiratory specimens that have acid-fast bacilli (AFB) on microscopy, or (especially) both. Pleural TB disease cases require sputum analysis to rule out pulmonary involvement.
- Persons with AFB sputum smear negative results are less likely to be infectious but are still capable of infecting others.

The primary goal of a contact investigation is to identify persons who were exposed to an infectious case of TB and ensure that contacts receive these evaluation services:

- Testing for *M. tuberculosis* infection
- Screening for TB disease
- Medical evaluation, if indicated
- Prompt initiation of treatment for latent tuberculosis infection (LTBI) if at high risk for developing TB disease (younger than five years of age or immunocompromised)
- A complete, standard course of treatment, unless medically contraindicated

In addition, the following are secondary goals of a contact investigation:

- Stop transmission of *M. tuberculosis* by identifying persons with previously undetected infectious TB.
- Determine whether a TB outbreak has occurred (in which case, an expanded outbreak investigation should ensue).

DECISION TO INITIATE CONTACT INVESTIGATION

The Program determines if a case meets criteria for investigation. Due to the availability of NAA rapid testing (e.g., MTD, GeneXpert, Accuprobe), investigations are not initiated without a NAA or culture positive test result. Exceptions are possible if rapid testing results are expected to be delayed and high priority contacts including children under the age of five, HIV+, or other high-risk contacts live in the household. In these circumstances, testing should be limited to the immediate household until confirmation of infectious TB has occurred. In the event TB has been ruled out, the results of the investigation are not reportable for purposes of CDC Aggregate Report.

If the case requires an investigation, the Program notifies the LPHA and together they determine individuals who should be evaluated. The Program will assign the case for investigation into IDSS under the 'TB Contacts' tab. The Program is the only entity with the authority to assign cases in IDSS for contact investigation. IDSS automatically notifies the LPHA of the assigned case for investigation when the Program designates the LPHAs responsible for investigation.

ASSIGNED RESPONSIBILITIES FOR CONTACT INVESTIGATIONS

LOCAL PUBLIC HEALTH AGENCIES

LPHAs are responsible for conducting contact investigations in all settings with the exception of health care facilities (HCFs). LPHAs should contact the director of nursing/infection control or other appropriate staff of HCFs to inform them of the exposure and provide guidance on conducting the contact investigation.

COVERED PUBLIC HEALTH CHARGES

PPD and /or IGRA for designated contacts. Arrangements for these testing materials must be authorized by the Program. In extenuating circumstances, medical evaluation charges for exposed contacts to include medical appointments, lab charges and chest-x ray. . CT scans are not covered. The Program provides medication for the treatment of LTBI and TB disease.

HEALTH CARE FACILITIES (HCFs)

HCFs are responsible for conducting contact investigations in their settings. HCFs are responsible for identifying HCWs, residents and or visitors in need of evaluation.

Covered Public Health Charges

HCFs are responsible for the cost of testing and follow up medical evaluation to include cost of PPD and/or IGRA. Use of the state hygienic lab for IGRA is appropriate; however, the cost is not a public health charge.

HCFs typically provide for any follow up medical evaluations related to a positive TB test to include cost of medical evaluation, CXR and subsequent lab monitoring. Public health provides medication for the treatment of LTBI and TB disease.

Important Differences Between LPHAs Contact Investigations vs. HCFs Contact Investigations:

HCFs often test more potentially exposed persons than LPHAs based upon existing (internal) HCF policy. For instance, HCFs may choose to evaluate all HCWs (including all shifts) who worked on the same floor where an infectious TB patient was roomed. Many of these contacts would appropriately be classified as low priority contacts by the LPHAs. However, due to the fact they are HCWs, they are automatically designated as high priority contacts, even if exposure levels are deemed low.

In contrast, LPHAs will evaluate **only** high or medium priority contacts to determine if there is evidence of transmission. If evidence of transmission exists, then LPHAs continue to evaluate contacts until the data (test results) demonstrate no evidence of transmission. As a result, LPHAs typically evaluate far less contacts than HCFs.

COLLEGES/UNIVERSITIES OR SIMILAR INSTITUTIONS

TB Screening: Some institutions, especially those with established student health centers, conduct screening of students for TB risk factors. Students with identified risk factors are tested for LTBI.

Contact Investigations: If the Program determines a TB case meets criteria for a contact investigation, it is the responsibility of the LPHA to conduct contact investigations for exposure to infectious TB. In practice, the LPHA and the college/university will work closely together on the investigation in identifying students and staff in need of evaluation. LPHA determines the direction and extent of the contact investigation.

TIMELINES

Consultation with the LPHN or designee investigating the case is initiated within one business day of determination that a patient has infectious TB. Classification of contacts into high, medium, or low priority is determined in accordance with current guidelines. See [Classification of Contacts: Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis Recommendations from the National Tuberculosis Controllers Association and CDC.](#)

Type of Contact	Business days from listing of a contact to initial encounter	Business days from listing of a contact to completion of medical evaluation
High-priority contacts	7	5
Medium-priority contacts	7	10
Low-priority contacts	14	10

CONTACT INVESTIGATIONS REPORTING REQUIREMENTS

The Iowa Administrative Code requires (641—1.7(135,139A)) (Appendix 1) LPHAs to report the results of public health investigations to the Department, however, it does not designate by which means this should be accomplished. Department preference is for LPHAs to manage and report results of investigations into IDSS TB Contacts. In cases where the LPHAs choose not to use IDSS for reporting purposes, the LPHA submits complete test results for those individuals determined to have exposure to infectious TB. The Program enters this data into IDSS for purpose of aggregate reporting to CDC.

RELEVANT ASPECTS OF CONTACT INVESTIGATIONS

COMPONENTS OF MEDICAL EVALUATION FOR EXPOSED CONTACTS

All identified contacts should be evaluated with TB skin test or Interferon Gama Release Assay (IGRA). The Programs recommendation is for LPHAs to use IGRAs to avoid the high rate of false positive test results associated with the TB skin test. There is no charge to the LPHA or the patient for this testing; it is paid for by the Program through an agreement with the State Hygienic Lab (SHL). LPHAs must contact SHL directly to arrange for blood collection kits, incubation procedures and courier transport of specimens.

The LPHAs should give priority to evaluating and testing all identified contacts during the first, and if necessary, second rounds of investigation. Contacts with a positive TST or IGRA require a medical evaluation including a chest X-ray to rule out active TB disease. Contacts requiring medical evaluation with no or limited ability to pay are eligible for medical evaluation funding. The Program will initiate a memorandum of understanding (MOU) with the LPHA to provide this funding. Details of the MOU are as follows:

Reimbursement for Medical Evaluations

- Cap Rate: \$300 per case
- Provide funds for barrier free TB medical services to high-risk groups with no means of payment
- Services include payment for office visits, chest x-rays, and lab work-up
- Reimbursements rates for specific services should be at the local T19 rate and negotiated by the LPHA and the service provider.

TREATMENT OF INFECTED CONTACTS

Identification and subsequent treatment of contacts with LTBI is a national objective for TB programs. As such, the Program strongly recommends the use of twice weekly DOT for all identified contacts with LTBI discovered as a result of the contact investigation. The Program is required to report on treatment initiation and treatment completion for this sub-set of contacts in the annual CDC Aggregate Report.

SITE VISITS

Failure to visit potential sites of transmission, such as patient's home, school, workplace, and frequent social sites (church, bar, etc.) has contributed to previous TB outbreaks. As part of the consultation on managing the contact investigation, the Program instructs the LPHN or designee on the importance of visiting relevant potential sites of transmission.

It is imperative that public health officials, working closely with appropriate personnel of entities where possible exposure to infectious TB occurred, determines those in need of evaluation, **not** personnel of said entities. Exposure to infectious TB in certain situations (schools, daycare, corrections, etc.) often results in officials of those entities demanding LPHAs test all/other selected persons for testing. LPHAs should consult with the Program on each investigation, especially those involving work and/or school site investigations.

Contact investigations in work site investigations may result in media attention. Companies often request the Program develop a news release for distribution to employees and/or the media. See SOP folder (Attachment 15). No identifying information may be released concerning the patient or the facility where suspected exposure has occurred. For overview of the IDPH policy, see the [Media, Legislative and Public Communications Policy](#).

TIMELINES

The Program will assign cases into IDSS within two business days of determination that a case meets criteria for investigation. The Program will monitor each investigation for the evaluation, treatment, and follow-up of identified contacts and will contact LPHAs that have not completed necessary fields to facilitate proper documentation of the contact investigation. Additional timelines for Program to contact LPHN or designee for common identified issues:

- No contacts entered: 14 business days after interview
- No 1st round test results entered/incomplete information: 14 business days after testing
- No 2nd round test results entered/incomplete information: 14 business days after testing
- Treatment completion not recorded for contacts who started treatment: 30 business days after scheduled treatment completion

SPECIAL CIRCUMSTANCES

High Risk Contacts: children less than 5 years of age

Children younger than 5 years of age are more susceptible to TB disease and more vulnerable to invasive, fatal forms of TB disease, such as TB meningitis. Because of this, the Program deems them a high priority contact during investigations and recommends they receive a full diagnostic medical evaluation including a TB skin test and a chest x-ray, regardless of TB skin test result (negative or positive). If the parent/guardian refuses evaluation for the child, consideration should be given to issuing the template 'Order for Diagnostic Evaluation– Minor' (Appendix 4). See section: *Diagnostic Evaluation Order: Adults and Children* for more information.

If the LPHA determines that child/children younger than 5 years of age may have been exposed to infectious TB, the LPHA should issue the parent/guardian of said minor '*Recommendation for Window Period Prophylaxis (WPP)*'. (Appendix 3)

- **Window Period:** The period of time between which a person is exposed to an infectious organism (TB) and when that organism (TB) becomes detectable via a test (TB skin test). For children younger than 5 years of age who have been exposed to someone with infectious TB, the window period is the interval between the first and second round of testing (8 – 10 weeks).
- **Prophylaxis:** Taking medicine to prevent a disease. For children younger than 5 years of age who have been exposed to someone with infectious TB, it is recommended they take an antibiotic (INH) during the window period to prevent the development of TB disease.

The reasons for WPP should be clearly explained to the parent/guardian and signature of the parent/guardian obtained, regardless of acceptance/rejection of WPP. **If WPP is rejected, document the reasons for rejection specifically noting that the parent/guardian understand that fatal TB is a medical possibility if WPP is not used.**

High Risk Contacts: Children ages 5 – 17 years

Minors in this high-risk category include children who have not been properly evaluated for exposure to infectious TB. It is intended for children who do not fall into the 'Children less than 5 years of age' category, but may be used for any child considered a minor. If this situation occurs, consideration should be given to issuing the template '*Order for Diagnostic Evaluation– Minor*' (Appendix 4).

Diagnostic Evaluation Order: Adults and Children

A person diagnosed with extrapulmonary TB or clinically suspected of having infectious TB who fails to comply with a physician's recommendation for diagnostic testing may be ordered to undergo diagnostic testing by the Program or local board of health. The intent of this action is twofold:

- To keep patients with confirmed extrapulmonary TB who chooses to stop taking TB medication, from subsequently developing infectious pulmonary and or laryngeal TB.
- To complete the diagnostic evaluation of person's clinically suspected of having infectious TB.

The diagnostic evaluation may include, but is not limited to, a physical examination, a chest x-ray or CT, and bacteriologic examinations at intervals established by the treating clinician and the LPHA.

Untreated patients with extrapulmonary TB are at risk for developing infectious TB, especially those with weakened immune systems (e.g., HIV+, other medical conditions).

Other scenarios that warrant an order to undergo evaluation include a child whose parent(s)/guardians did not present the child for evaluation, despite written request to do so.

Templates to be used are the '*Order for Diagnostic Evaluation – Minor*' (Appendix 4) or '*Order for Diagnostic Evaluation – Adult*' (Appendix 5).

CHAPTER 7: DISCHARGE PROCEDURE

LTBI

Treatment for LTBI is not reportable or mandatory. As such, after the prescription is sent out to the LPHA, the Program does not actively monitor the treatment for the patient. The LPHA should distribute medication one month at a time and monitor for adherence and adverse reactions to medication on a monthly basis. The LPHA may inform the Program of patient adherence/complications, of which the Program documents in TB Meds program.

If the LPHA has a patient who medication was ordered, and they are unable to contact them by phone for medication pick-up, the LPHA is encouraged to send a notification letter by certified mail to the patient. If that letter goes unanswered or is returned, the LPHA can consider the case closed and notify the Program of closure.

The Program does not provide routine completion information to prescribing providers. If a provider contacts the program and requests information on specific clients, it will be provided.

SUSPECTED/CONFIRMED TB DISEASE

Reported cases are discharged from the Program when treatment is completed to cure. Cases with incomplete treatment are evaluated individually as to why therapy was stopped and the appropriate-defined variable '*Reason Therapy Stopped*' is documented in IDSS. If warranted, possible legal intervention by the LPHA and/or the Program should be considered for pulmonary/laryngeal TB cases that do not complete treatment. Patients with untreated or incomplete treatment for extrapulmonary TB are at risk for developing infectious TB, especially those with weakened immune systems (e.g., HIV+, other medical conditions). Suspected TB disease cases ruled out have no formal discharge procedure.

CHAPTER 8: COHORT AND CASE REVIEWS

Cohort reviews are a systematic review of the management of patients with TB disease and their contacts. A 'cohort' is a group of cases counted over a specific period of time. Emphasis is placed on the patient's clinical status, adequacy of treatment regimen, treatment adherence or completion, and the results of contact investigation.

Frequency: Cohort cases are reviewed approximately six to nine months after treatment initiation, thus, many of the cohort cases have completed or are near treatment completion. The Program will select cases for review and arrange for systemic review annually.

Personnel: Involved personnel shall include the Program Manager and Nurse Consultant, TB Medical Consultant (Dr. Hornick), State Medical Director or designee, the LPHN or designee handling the case, and if possible, the treating clinician.

Reporting Requirements: Includes a summation of the date cohort review occurred, the number/type of cases reviewed, and aggregate report of selected performance objectives for the cohort will be submitted to CDC following the review.

Case reviews occur monthly

CHAPTER 9: REFUGEE HEALTH

The Refugee Health Program is a separate and distinct program from the TB Control Program. However, a significant proportion of refugees receive a Class A or B TB designation, thus, there is significant overlap between the two programs. The Refugee Health Specialist has been assigned the duty to monitor and track all refugees and immigrants who receive a Class A or B TB designation. Immigrants and refugees are both political classifications and assigned by the U.S. Department of State. The Refugee Health Program does not track immigrants unless they have received a Class A or B designation. In doing so, the Refugee Health Specialist is performing these duties in cooperation with the TB Control Program and with oversight by the TB Program Manager.

CLASS A OR B NOTIFICATIONS

Domestic follow-up evaluation of immigrants and refugees with Class A, B1 and B2 TB page 21 of [Technical Instructions for Tuberculosis Screening](#). Notification status is deemed a high priority by the Program. The Refugee Health Specialist is responsible for daily monitoring and receiving of notifications from the Electronic Disease Notification system (EDN). Newly arrived refugees and immigrants with Class A or B TB will receive thorough and timely TB evaluations and appropriate treatment to ensure prompt detection of TB disease and prevention of future cases.

All Class B designees are to receive an evaluation within 90 days of arrival to Iowa. The Refugee Health Specialist works directly with the Program, resettlement agencies and LPHAs to accomplish this goal.

Click [here](#) for detailed overview of the domestic refugee health screening programs, differences between political designations of immigrants and refugees and current medical screening recommendations. See '[Technical Instructions for Tuberculosis Screening and Treatment](#)' for detailed overview of CDC overseas TB screening program for refugees and immigrants.

CLASS A OR B PROCEDURE

Review EDN daily for new notifications.

- Class A or B: Print/fax all medical records including '[TB Follow-Up Worksheet](#)' (Appendix 11) and '[TB Follow-Up Recommendations](#)' (Appendix 12) to LPHA.
- Record data into the Class B TB Tracking System.
- LPHAs return follow-up information to the Program. Relevant information is recorded in the EDN system and submitted to Division of Global Migration and Quarantine (DGMQ).
- Dual entry in the 'Class B TB Tracking System' completes the data entry.
- Follow-up on incomplete or non-returned TB Follow-up Worksheets is done by the Refugee Health Specialist.

REFUGEE HEALTH INTAKE PROCEDURE

- Review EDN daily for new notifications.
- All refugees, with or without a Class B designation, are tracked in the Refugee Health System.
- The resettlement agency assigned to a particular refugee is notified of EDN notification. Verification of EDN records with resettlement agency records occurs monthly to ensure accounting of all refugees in Iowa.
- Working in cooperation with the appropriate resettlement agency, all refugees should receive a domestic health screening utilizing the '[Iowa Refugee Health Assessment](#)' form (Appendix 13).
- No electronic re-submission of completed Iowa refugee health assessments are requested by DGMQ; however, aggregate analysis of this objective is reportable in the annual progress report.
- Clinics currently are not required to return health assessments, however it is recommended. The Refugee Health Specialist makes contact with clinics that do not return assessments to ascertain if assessments can be submitted to the Program for data collection purposes.

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<i>Appendix 5:</i>	<i>Order for Diagnostic Evaluation – Adult</i>
<i>Appendix 6:</i>	<i>DOT Tracking Log</i>
<i>Appendix 7:</i>	<i>Notification of Voluntary Treatment Responsibilities for Infectious Tuberculosis</i>
<i>Appendix 8:</i>	<i>Notification of Voluntary Home Confinement for Infectious Tuberculosis</i>
<i>Appendix 9:</i>	<i>Facility Isolation Order</i>
<i>Appendix 10:</i>	<i>Travel Restriction Guidance</i>
<i>Appendix 11:</i>	<i>Refugee Health Program TB Follow-Up Worksheet</i>
<i>Appendix 12:</i>	<i>Refugee Health Program TB Follow-Up Recommendations</i>
<i>Appendix 13:</i>	<i>Refugee Health Program Assessment Form</i>
<i>Appendix 14:</i>	<i>IDPH Investigation Brief Template</i>
<i>Appendix 15:</i>	<i>Template: Worksite Investigation</i>
<i>Appendix 16:</i>	<i>TB Warning Letter Template</i>
<i>Appendix 17</i>	<i>Iowa TB and Communicable Disease Investigation Citations</i>